

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 21 MAR 2006

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|--|--|--|-----------------------|
| Applicant's or agent's file reference IC/00S458WO | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/NZ2005/000002 | International filing date (<i>day/month/year</i>) 19 January 2005 | Priority date (<i>day/month/year</i>) 5 February 2004 | |
| International Patent Classification (IPC) or national classification and IPC | | | |
| Int. Cl. | | | |
| G01N 21/41 (2006.01) | C12N 5/06 (2006.01) | G01N 21/64 (2006.01) | |
| Applicant SELECT XY LIMITED et al | | | |

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☒ (sent to the applicant and to the International Bureau) a total of 5 sheets, as follows:
 - ☒ 5 sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
- This report contains indications relating to the following items:

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|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

| | |
|---|--|
| Date of submission of the demand 29 June 2005 | Date of completion of this report 13 March 2006 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer Sophina Calanni Telephone No. (02) 6283 2038 |

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ The international application in the language in which it was filed
- ☐ A translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1 (b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages **1-17** as originally filed/furnished

pages* received by this Authority on _____ with the letter of _____

pages* received by this Authority on _____ with the letter of _____

☒ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* **19-20** received by this Authority on **29 June 2005** with the letter of **27 June 2005**

pages* **21-23** received by this Authority on **7 March 2006** with the letter of **7 March 2006**

☒ the drawings:

pages as originally filed/furnished

pages* received by this Authority on _____ with the letter of _____

pages* received by this Authority on _____ with the letter of _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Claims 1-37 | YES |
| | Claims | NO |
| Inventive step (IS) | Claims 1-37 | YES |
| | Claims | NO |
| Industrial applicability (IA) | Claims 1-37 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 US 5,135,759 A (Johnson, Lawrence A.) 4 August 1992

D2 WO 2001/085913 A2 (XY Inc.) 15 November 2001

D3 Rens, W et al., 1998, *Cytometry*, 33: 476-481

D4 Kay, D.B. and Wheeless, L.L., 1976, *Journal of Histochemistry and Cytochemistry*, 24: 265-268.

D5 Kay, D. B. and Wheeless, L.L., 1977, *Journal of Histochemistry and Cytochemistry*, 25: 870-874.

D6 Welch, G.R. and Johnson, L.A., 1999, *Theriogenology*, 52: 1343-1352.

D7 Johnson, L.A. and Welch, G.R., 1999, *Theriogenology*, 52: 1323-1341.

D8 Sharpe, J.C. et al., 1997, *Cytometry*, 29: 363-370.

The present invention relates to a method for determining the orientation of an aspherical cell, for example sperm. In particular, the applicant's have shown that the orientation of a sperm cell can be determined by passing light using optical phase contrast or Dark field technologies through the sperm cells. Those cells possessing the correct orientation, as determined by measuring the non-fluorescent light emitted by the cell, can then be selected for further analysis (p. 8 lines 8 -37). The use of phase contrast or dark field optical techniques to measure non-fluorescent light emitted by the cell as a means to determine the orientation of an aspherical cell provides several advantages over prior art techniques including higher processing speeds and no requirement for encapsulation within an electrically charged medium during analysis and collection phases.

Supplemental Box I

In case the space in any of the preceding boxes is not sufficient.

Continuation of Box V Reasoned statement with regard to novelty, inventive step or industrial applicability

Novelty (N) and Inventive Step (IS)

D1-D3, D6-D8 describe various flow cytometric techniques for sorting aspherical cells (eg sperm) based on assessing the DNA content of said cells. The methods described do not use phase contrast or dark field optical techniques to determine the orientation of the aspherical cell.

D4 and D5 describe the use of dark field laser stroboscopic images to determine the orientation of cells flowing through a laser beam. The citations do not disclose the selection of cells for use in a second method wherein a desired cell is selected based on differences in size, mass, volume or density.

As such, the prior art published before the priority date does not disclose nor suggest to the person skilled in the art that phase contrast or dark field optics can be used to determine a desired cells orientation and then used in a second method to select particular cells based on differences in size, mass, volume or density. Therefore, claims 1-38 meet the criteria set forth in PCT Article 33(2) and 33(3) with regard to novelty and inventive step.

Industrial Applicability (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT.